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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,674	11/17/1999	MARK E. LEWIS	6622.US.01	4770

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EXAMINER

CROSS, LATOYA I

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/441,674	Applicant(s) LEWIS ET AL.	
	Examiner LaToya I. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-22, 24 and 26-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-22,24 and 26-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

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## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 17, 2002 has been entered. Claims 1, 4-24 and 26-62 are pending.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 9, 10, 12-18, 21-24, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,580,794 to Allen (hereinafter Allen '794).

Applicants' invention is directed to a test strip for use in combination with a measuring device comprising a support, at least one reaction area, and an indicator.

Allen '794 teaches a disposable electronic assay device. The device comprises a test strip containing a sample receptor for receiving a sample to be tested, a sample treatment element for reaction with the sample to yield a detectable change, an electrical signal produced by a detector to correlate the amount of analyte in the sample, and a signal processor for outputting a visually readable result. See abstract. The test strip (10) has a pair of electrodes

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(12) mounted between the sample receptor zone (14) and the reagent zone (16). (col. 7, line 62 – col. 8, line 15). The reagents may be dry formulated on a matrix which can be a bibulous material such as porous plastic (col. 10, lines 33-43). The reagent zone may comprise reagents such as enzymes, antibodies, antigens, etc. (col. 16, lines 16-21). The detectable change is a change in reflectivity, transmission or electrical current (col. 7, lines 41-61). The signal processing means may include an analog to digital conversion means. Assays for glucose, cholesterol, triglycerides, etc. may be detected by the devices. In addition, single or multiple assays can be done at one time.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b), in view of the teachings of Allen '794.

4. Claims 1-8, 10-22, 24, 26 and 28-62 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,312,590 to Gunasingham (hereinafter Gunasingham '590).

Gunasingham '590 teaches a device for detecting chemical species in liquids.

The test device comprises measuring electrodes (2) and reference electrodes (4) coated with a reaction layer (11) and a membrane layer (12). At least one of the electrodes is made by screen-printing carbon ink onto the base strip (1), as recited in claims 37, 48, and 59 (col. 6, lines 35-37). Each of the electrodes is made of gold, platinum, silver, graphite, etc, as recited in claims 36, 47, and 58. The measuring apparatus used in conjunction with the test device connects to the reference/working electrode pairs. The device is used in sensing blood glucose levels using the enzyme glucose oxidase, as recited in claims 30-34, 41-45 and 52-56. With respect to claims 38, 39, 49, 50, 60 and 61, Gunasingham teaches the electrode being on one part of the test strip surface and the indicator being on another part of the test strip. See figure 8. Since

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Applicants' are unspecific as to what they intend "major surface" to mean, the Examiner takes the position that each part of the test strip would constitute a major surface. With respect to claims 29 and 51, Gunasingham teaches multiple holes. While these holes may not be used for the same functions Applicants recite, functional differences from the prior art cannot be used to distinguish the claimed invention. See MPEP 2114.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102, in view of the teachings of Gunasingham '590.

### ***Response to Arguments***

5. Applicant's arguments filed December 17, 2002 have been fully considered but they are not persuasive. Applicants' argue that neither Allen nor Gunasingham teach that the indicator on the test strip allows the measuring device to differentiate between two or more types of test strips to select at least one of a multiplicity of testing functionalities of the measuring device. Applicants' claims do not recite the indicator to differentiate between two or more types of test strips. Applicants' claim recites that the indicator is capable of selecting at least one of a multiplicity of testing functionalities of said measuring device. This limitation can be construed more broadly than Applicants' intend. Allen and Gunasingham both teach that single or multiple assays can take place. Since Applicants' claim recites, "select at least one of said multiplicity of testing functionalities", the disclosure of Allen and Gunasingham reads on the claim. The claim is not limited to selecting one functionality; neither does the claim exclude conducting multiple tests "at the same time". Thus, both Allen and Gunasingham read on the claimed invention.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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March 24, 2003

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700